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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/019,049	03/28/2002	Jorg Rosenberg	0480/01221	5165

7590 04/22/2003

Keil & Weinkauff  
1101 Connecticut Avenue NW  
Washington, DC 20036

EXAMINER
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FUBARA, BLESSING M

ART UNIT	PAPER NUMBER
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1615

DATE MAILED: 04/22/2003

*Restart 2/2/04 8*

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Applicati n No.</b>	<b>Applicant(s)</b>	
	10/019,049	ROSENBERG ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Blessing M. Fubara	1615	

-- The MAILING DATE of this communicati n appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-6 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-6 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☒ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                  | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). ____.  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>6</u> . | 6) <input type="checkbox"/> Other: _____                                    |

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### **DETAILED ACTION**

Examiner acknowledges receipt of declaration and preliminary amendment A filed 03/28/02, IDS filed 10/29/02 and change of address filed 03/04/03.

#### ***Specification***

This application is a 371 of PCT/EP00/05848 filed 06/23/2000. It is suggested that the specification be amended where the statement --- This application is a 371 of PCT/EP00/05848 filed 06/23/2000--- is inserted on the first line below the title.

#### ***Priority***

1. Acknowledgment is made of applicant's claim for foreign priority based on an application filed in Germany on 07/02/1999. It is noted, however, that applicant has not filed a certified copy of the German application as required by 35 U.S.C. 119(b).

#### ***Claim Rejections - 35 USC § 102***

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1-3 are rejected under 35 U.S.C. 102(b) as being anticipated by Krape et al. (WO 99/00131, provided by applicants on Form PTO-1449).

Krape discloses solid dispersion of paroxetine in polyvinylpyrrolidone or polyethylene glycol polymeric carrier (abstract, page 5, lines 31-34). In a preferred embodiment, Krape discloses a process for forming the paroxetine-HCl polymer melt that involves heating a mixture

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of the paroxetine and polymer carrier to form a molten homogenous melt of paroxetine free base and the polymeric carrier and introducing dry hydrogen chloride into the vessel where a pharmaceutically acceptable paroxetine-HCl is formed in the molten state (page 6, line 27 to page 7 line 7). In example 1, Krape forms a homogenous melt of paroxetine free-base and PEG in a flask and subsequently scraps the product from the flask to grind or mill into desired particle size.

The claimed invention is directed to a solid or semisolid preparation of paroxetine or one of its physiologically acceptable salt in the form of a molecular dispersion of paroxetine in a pharmaceutically acceptable polymer matrix having a glass transition temperature of  $>90^{\circ}\text{C}$ . The instant specification on page 1, lines 36-41, describes dispersions of two or more solids as solid solutions or molecular dispersions. The melt of paroxetine and polymer carrier in Krape is a solid solution or molecular dispersion of paroxetine in a polymer. No specific polymer is claimed in the instant invention. The glass transition temperature of a polymer is specific to a specific polymer. Thus the recited glass transition temperature of  $>90^{\circ}\text{C}$  is inherent to the polymeric carrier of the prior art. Paroxetine-HCl is formed when dry hydrochloric acid is introduced into the homogenous melt of the polymeric carrier and paroxetine free-base and this teaching meets the limitation of claim 2. In instant claim 3, 80% of the active ingredient is released after 30 minutes and this property is inherent to the paroxetine formulation of Krape. Thus, the teaching of Krape anticipates the claims.

Krape is published on 07 January 1999, which is greater than one year from the PCT filing date of 06/23/00 but less than a year from the foreign priority date of 07/02/1999.

However, the art is used as a 102(b) because applicants neither submitted a certified copy of the

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priority document nor provided a translation of the priority document. Submission of certified copy of the foreign priority document and a proper English translation of the priority document would remove the prior art as a 102(b) art.

***Claim Rejections - 35 USC § 103***

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 4-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Krape et al. (WO 99/00131) in view of Craig et al. (WO 00/32593) and further in view of Patel et al. (US 6,248,363).

The teaching of Krape is discussed above. Claim 6, which is dependent on claim 5, is taught in Krape because Krape employs paroxetine free-base in the formation of molten homogenous melt of paroxetine-HCl and polymer. Although Krape discloses forming a homogenous melt of paroxetine-HCl and polymeric carrier and optionally grinding or milling the melt to desirable particles (example 1 of Krape), Krape's melt was formed in a flask and not in an extruder. Thus regarding claim 4, Krape does not teach forming the melt in an extruder. However, Patel teaches solid carriers for pharmaceutically active ingredients (title). In Patel, paroxetine is one of the pharmaceutically active ingredients (column 5, line 61 and column 9, line 9). The formulation of Patel contain polymeric additives (column 39, lines 41) and the dosage form comprising the pharmaceutical agent, polymeric additives, surfactants (column 10, line 41), triglycerides (column 32, line 61) and solubilizers (column 37, line 25) is extruded or

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melted or compressed or wet granulated or dry granulated (column 41, lines 27-46). Patel further discloses that components are melt extruded (column 47, lines 13-18). Patel is thus relied upon for melt extruding carrier formulations comprising pharmaceutical agents of which paroxetine is listed. The Patel reference shows that paroxetine containing compositions can be melt extruded. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to extrude the homogenous melt of Krape with the expectation that the molten paroxetine-HCl and the polymeric carrier would be formed into particles. One having ordinary skill in the art would have been motivated to extrude the homogenous melt of Krape in order to shape/grind/mill the melt into the desired particles size.

Regarding claim 5, Krape does not teach forming paroxetine-HCl with ammonium chloride. But Craig discloses that paroxetine-HCl can be formed by reacting paroxetine base or salt with an amine hydrochloride such as ammonium chloride with the proviso that the paroxetine salt is not paroxetine acetate or paroxetine tartrate (page 2, lines 11-17 and page 3, lines 31 and 32). Craig is relied upon for a teaching that paroxetine-hydrochloride salt can be prepared from paroxetine base or salt and ammonium chloride. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to prepare paroxetine-HCl according to the teaching of Krape. One having ordinary skill in the art would have been motivated to substitute ammonium chloride for hydrochloric acid with the expectation for the formation of paroxetine-HCl.

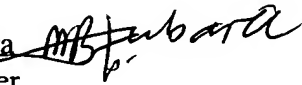
6. The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicants' cooperation is respectfully requested in correcting any errors of which applicants may become aware in the specification.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Blessing M. Fubara whose telephone number is 703-308-8374. The examiner can normally be reached on 7 a.m. to 3:30 p.m. (Monday to Friday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on 703-308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3592 for regular communications and 703-305-3592 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1234.

Blessing Fubara   
Patent Examiner  
Tech. Center 1600  
April 21, 2003